DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 20, 2015

Acclarent, Inc.
Pavan Sethi, PhD
Manager, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K150453
Trade/Device Name: Tula Iontophoresis System with Earset
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class III
Product Code: EGJ
Dated: April 21, 2015
Received: April 22, 2015

Dear Dr. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S
for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150453

Device Name
TULA® Iontophoresis System with Earset

Indications for Use *(Describe)*
The Iontophoresis System with Earset is indicated for the administration of drug solution, salts, or ions into the ear, including the tympanic membrane, for medical purposes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Pavan Sethi, Ph.D. Manager, Regulatory Affairs Phone: (650) 687-5413 Fax: (650) 687-4847
Date of Submission:	February 19, 2015
Device Trade Name:	TULA® Iontophoresis System
Common Name:	Iontophoresis System with Earset
Device Classification:	Class III
Regulation Number:	21 CFR 890.5525
Classification Name:	Device, Iontophoresis, Other Purposes
Product Code:	EGJ
Predicate Device:	Iontophoresis System with Headset or IPSHS (K110636) manufactured by Acclarent
Device Description:	The Acclarent Iontophoresis System with Earset (IPSES) is a single-use device that employs electric current to transport drug solution, salts, or ions into the ear, including the tympanic membrane. The TULA Iontophoresis System consists of three components, namely an Iontophoresis Control Unit, Iontophoresis Earsets and a Return Electrode Patch. Accessories to the IPSES include a Syringe and Earset Sizers. All components of the IPSES are provided non-sterile and no sterilization is required.
Indications for Use:	The Iontophoresis System with Earset is indicated for the administration of drug solution, salts, or ions into the ear, including the tympanic membrane, for medical purposes.
Technological Characteristics:	IPSES delivers an electrical current to the ear. The electrical current transports drug solution, salts, or ions into the ear, including the tympanic membrane. The subject device is identical to the predicate device in method of operation and intended use. The Iontophoresis process and the components controlling it including Control Unit, Integrated Ear Electrode and Return Electrode Patch are unchanged between the subject and predicate device. The main differences in technological characteristics include, modification of the mechanism to

	retain the ear plug in the external ear canal and integration of ear plugs into the design of the earset instead of being a separate accessory in the predicate Headset device. In the predicate device, the ear plug is attached to the Headset and retains the fluid (drug solution, salts, or ions) within the ear canal by forming a seal. The modified device integrates this ear plug into a smaller sized Earset to achieve an analogous seal. The predicate device uses a frame to maintain the Headset in position and a spring to hold the ear plug in the ear canal, whereas the modified subject device uses a small amount of soft pressure sensitive adhesive (PSA) to secure the ear plug to the patient. These differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate and do not render this device Not Substantially Equivalent (NSE).
Performance Data:	Bench verification testing was conducted to verify that the modified device meets the design inputs and intended performance characteristics. The testing included system test, ear canal pressure and leak test, fill system burst test, plug peel force test, tack force test, and biocompatibility tests. Electrical testing demonstrated that the subject device IPSES meets all applicable requirements of the standards of IEC 60601-1 and IEC 60601-1-2.
Summary of Substantial Equivalence:	The subject device IPSES is substantially equivalent to the predicate device in indication for use, performance, fundamental scientific technology, safety and effectiveness.